

REMARKS

I. Status of the Application

Claims 10, 13, 14, 16-18, 20-23, 25, 26 and 28 are pending in the application. In the instant Office Action, claims 10, 13, 14, 16-18, 20-23, 25, 26 and 28 remain rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. Claims 13, 14, 23 and 28 have been cancelled without prejudice to the filing of any appropriate continuation applications.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Support for the amendments can be found in the specification and the claims as originally filed. Specifically, support for the amendments to claims 10, 20 and 25 to recite producing osteocalcin can be found in the specification at least at page 12 line 15, where Applicants teach osteocalcin release over time into culture medium. Support for the amendments to these claims to recite osteogenic cells can be found in the specification at least at page 5 line 21, where Applicants teach the osteogenic character of their culture system, and at page 12, lines 6-8, where Applicants teach osteogenic cells. Support for the amendments to claims 25 and 26 to recite bone marrow cells comprising stromal cells can be found in the specification at least at page 3 lines 23-24, where Applicants teach that bone marrow cells can include stromal cells. The amendments presented herein add no new matter.

Applicants respectfully request entry and consideration of the foregoing remarks, which are intended to place this case in condition for allowance.

II. The Pending Claims Are Enabled

At page 2, paragraph 4 and page 6, paragraph 1 of the Final Office Action, claims 10, 13, 14, 16-18, 20-23, 25, 26 and 28 remain rejected under 35 U.S.C. § 112, first paragraph, as

lacking enablement. The Examiner is of the opinion that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. The Examiner states that the specification is enabling for a method of producing osteocalcin comprising the steps of: (a) applying bone marrow cells on a substrate; (b) contacting the bone marrow cells with a culture medium; (c) inducing the bone marrow cells to differentiate into osteogenic tissue by one or more inductors of differentiation, wherein osteogenic tissue produces osteocalcin; and (d) recovering osteocalcin from the culture medium. The Examiner asserts that the specification does not reasonably provide enablement for a method of producing active factors or bone growth factors. The Examiner is of the opinion that the specification fails to teach the differentiation of stromal cells, but states that bone marrow cells can comprise stromal cells. Applicants respectfully traverse these rejections.

Without acquiescing to the Examiner's rejections, Applicants respectfully submit that the pending claims have been amended to expedite prosecution in view of the Examiner's comments. Specifically, the pending claims have been amended to recite a method of producing osteocalcin, and step (c) of independent claims 10, 20 and 25 have been amended to recite that, respectively, undifferentiated cells, bone marrow cells or bone marrow cells comprising stromal cells are differentiated into osteogenic cells.

Applicants incorporate herein the arguments presented in the Amendment and Response filed April 14, 2004. Briefly, Applicants reiterate that methods of applying undifferentiated cells on a substrate, contacting the cells with a culture medium, inducing the undifferentiated cells to differentiate and produce active factors, and recovering active factors from the culture medium use techniques that are well known by those of skill in the art in fields such as cell culture, cell

biology, transplantation and the like. Further, Applicants provide a working example wherein undifferentiated cells are added to a substrate in the presence of culture medium, the cells are induced to differentiate into cells having osteogenic character, and osteocalcin is produced (e.g., Example 1). Finally, the Examiner has indicated that the instant specification is enabling for a method of producing osteocalcin.

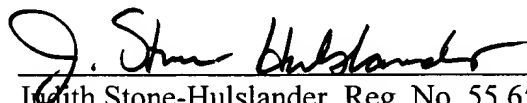
Applicants respectfully submit that the amended claims read in view of the teachings of the specification would enable one of skill in the art would be able to make and/or use the invention without undue experimentation. Accordingly, Applicants respectfully request that the rejection of claims 10, 16-18, 20-22, 25 and 26 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

III. Conclusion

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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